POLICY FORUM: INTELLECTUAL PROPERTY

Patents, Secrecy, and DNA

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The patent system has contributed greatly to genomics. More than 25,000 DNA-based patents were issued by the end of 2000 (*1*), covering purified and cloned gene fragments and full-length genes, regulatory sequences, sequencing and diagnostic methods, and many other inventions. The expectation of patents being granted is one reason that 73 publicly traded genomics firms were collectively valued at $96 billion at the end of 2000 (*2*). No other sector of the economy depends as much on strong patent protection or on the flow of information from academic science as pharmaceuticals and biotechnology (*3*, *4*).

The intellectual property regime for DNA sequences is trade secrecy when data are most valuable, followed by government-enforced monopoly rights for the duration of a patent's term (*5*–*12*). When patents remain pending for years, as they typically do in biotechnology and genomics, the DNA sequence information contained in a patent is usually known publicly from other sources by the time the patent is issued. A patent issued to Human Genome Sciences (HGS), for example, claims the gene for a protein that turned out to be the CCR5 receptor (*13*). Data available in the scientific literature when the patent was issued revealed DNA sequence errors in the patent (*14*). HGS's information would have been valuable to other researchers when the company first filed its application, but after 4 years and 8 months of patent examination, the public value of the sequence information was nil, Indeed, its quality inferior to data by then in the public domain. HGS investors may have hoped for this patent position, which would have required subsequent users to get a license from HGS or risk infringement litigation, and social value may accrue from inducing such private investment, but this patent illustrates the minimal informational value of many gene patents.

Most patent applications filed in the United States since 29 November 2000 will be published after 18 months (*15*), limiting the period of secrecy. The 18-month publication rule has long been in effect for patents submitted to international patent organizations such as the European Patent Office (EPO) and under the Patent Cooperation Treaty (PCT). An important exception remains, however, because applicants who are only filing in the United States and not in a country that has the 18-month publication rule can still keep their applications proprietary until a patent is issued. Thus, the 18-month rule may not result in disclosure of much more data but makes it more conveniently available in the United States. When Incyte and HGS decided not to file their initial DNA sequence-based patents abroad (*16*), they gave up patent rights in Europe and Japan as a consequence. This entailed a trade-off between charging for access to their databases and worldwide patent protection. They apparently judged that for partial gene sequences, the balance favored trade secrecy.

DNA-sequence databases, various patent offices, and a working group of the World Intellectual Property Organization (WIPO) getting under way will consider how DNA sequence information in patent applications can be submitted directly to public DNA sequence databases (*17*). This would make the data much more readily available and could also potentially open a path to publication of sequence data separately from, and earlier than, publication of the rest of the patent.

An inventor seeking worldwide patent rights cannot divulge the invention publicly before applying for a patent (*18*), but data can be published once an application is filed without sacrificing patent rights. An applicant can also request early publication of the entire patent application. Secrecy is necessary only until the application is filed. What is missing is a norm of disclosure immediately, or at least soon, after applying for a patent.

Establishing a norm for public release of DNA sequence information contained in patent applications would restore the informational value of patents, would reduce duplication of sequencing efforts (which, in the absence of disclosure, do not even provide the advantage of replicating results), and would speed the flow of crucially important biological information throughout the innovation system. Licensing data in pending patents amounts to charging for access to trade secrets. Keeping sequence data secret after a patent application has been filed flies in the face of goals for research funded by both government and nonprofit organizations. A 1988 report suggested that federal funding agencies could make data release after patent application a condition of grants and contracts (*19*), but to our knowledge no agency or nonprofit funder has adopted this policy. Instead, many have developed ad hoc policies to encourage early disclosure of sequence data that apply only to a small subset of researchers, and may, in some cases, undermine the subsequent development of inventions by destroying the patent incentive (*20*). For private firms, such early sequence disclosure would be voluntary, but the innovation system as a whole (including private firms in aggregate) would operate more efficiently if such a norm took hold. In theory, patents need not hinder earlier public disclosure of valuable DNA sequence data, but can instead promote it.

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